

OCT 03 2008



Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet	1		6	Application Number	10/795,860
				Filing Date	2004-7-12
				First Named Inventor	Phillips, Jeffery O
				Art Unit	1616
				Examiner Name	Choi, Frank I.
				Attorney Docket Number	04242373

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Issued Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)	YYYY-MM-DD		
A1		5254682	1993-10-19	Dhanoa, et al.	

NON-PATENT LITERATURE	
Examiner Initials*	Cite No. <sup>1</sup>
	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	B1 ANSEL, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, p. 77, Williams & Wilkins, 6th ed. (1995)
	B2 BADER, et al., "An Open Trial of Omeprazole in Short-Term Treatment of Duodenal Ulcer", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 177-178 (1986).
	B3 BARON, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 117. (1986).
	B4 BARON, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 122 (1986).
	B5 BENDTSEN, et al., "Intraduodenal pH During Omeprazole Treatment in Duodenal Ulcer Patients", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 156-157 (1986).
	B6 BERGLINDH, Thomas, "How to Study Properties of a Terminal Step Acid-Secretory Inhibitor <i>In Vitro</i> ", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 47-48 (1986).
	B7 BERGLINDH, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 96-98 (1986).
	B8 BLOM, Hakan, "Effects of Omeprazole on Normal and Regenerating Gastric Mucosa in the Rat. A Light and Electron Microscopic Study", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 70-71 (1986).
	B9 BLUM, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 134-135(1986).
	B10 BRANDSTROM, et al., "Structure-Activity Relationship of Substituted Benzimidazoles", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 54-56 (1986).
	B11 BYROD, Eva, "Direction for Use of Omeprazole", pp. 1-3.
	B12 CARLSSON, et al., "Pharmacology and Toxicology of Omeprazole with Special Reference to the Effects on Gastric Mucosa", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 31-38 (1986).
	B13 COLIN-JONES, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 128 (1986).

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	B14	COLIN-JONES, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 187-194 (1986).
	B15	CREAN, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 46 (1986).
	B16	DAMMAN, et al., "Intragastric Acidity Under a 28-Day Omeprazole Treatment", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 154-155 (1986).
	B17	DARLE, et al., "Rate of Healing of Benign Gastric Ulcer During Treatment with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 180 (1986).
	B18	DELCHIER, et al., "Long-Term Treatment with Omeprazole in Seven Patients with Zollinger-Ellison Syndrome Resistant to H <sub>2</sub> -Antagonists", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 184-186 (1986).
	B19	DENT, et al., "Effects of Omeprazole on Peptic Oesophagitis and Oesophageal Motility and pH", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 181 (1986).
	B20	DIVE, et al., "Rate of Duodenal Ulcer Healing During Treatment with Omeprazole. A Double-Blind Comparison of a Daily Dose of 30 mg Versus 60 mg", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 175-176 (1986).
	B21	EARNEST, David, "Controlling Gastric pH: The Impact of Newer Agents on the Critically Ill Patient", DICP Ann. Pharmacother., Vol. 24 (Suppl.), pp. S31-S34 (1990).
	B22	FESTEN, et al., "The Effect of Oral Omeprazole on Gastric Acid and Pepsin Secretion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 158-159 (1986).
	B23	FESTEN, et al., "Effect of Oral Omeprazole on Fasting and Meal Stimulated Serum Gastrin and Serum Pepsinogen I Levels in Healthy Volunteers", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 160-161 (1986).
	B24	FIMMEL, et al., "The Effects of Omeprazole on Acid and Pepsin Secretion in the Isolated, In Vitro Perfused Whole Mouse Stomach", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 68-69 (1986).
	B25	FLEMSTROM, et al., "Effects of Omeprazole on Gastric and Duodenal Bicarbonate Secretion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 65-67 (1986).
	B26	FORSSELL, et al., "Structure and Function of the Dog Gastric Mucosa During and After a 1-Year Treatment with Omeprazole. I. Macro- and Microscopic Findings", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 79-81 (1986).
	B27	HAKANSON, et al., "Gastrin and the Trophic Control of Gastric Mucosa", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 18-30 (1986).
	B28	HANSSON, et al., "Toxicology Studies with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 89-91 (1986).

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B29	HOWDEN, et al., "An Investigation into the Effects of Omeprazole on Renal Tubular Function and Endocrine Function in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 169-170 (1986).
B30	HUTTEMANN, W., "Short-Term Treatment of Gastric Ulcer with Once Daily Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 179 (1986).
B31	KITTANG, et al., "Effect of Omeprazole on the Secretion of Intrinsic Factor, Gastric Juice and Pepsin in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 162-163 (1986).
B32	LAMERS, Cornelis, "Present Experiences with Omeprazole in the Zollinger-Ellison Syndrome", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 123-127 (1986).
B33	LARSEN, et al., "Effects of Omeprazole and Cimetidine on Mucosal Acid Secretion, Blood Flow and Oxygen Consumption in the Dog <i>Ex Vivo</i> Gastric Chamber", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 61-64 (1986).
B34	LARSSON, et al., "Animal Pharmacodynamics of Omeprazole. A Survey of its Pharmacological Properties <i>in vivo</i> ", Scand. J. Gastroenterology, Vol. 20, Suppl. 108, pp. 23-35 (1985).
B35	LARSSON, et al., "Inhibition of Rat Gastric H <sup>+</sup> -K <sup>+</sup> -ATPase <i>In Vivo</i> . Relation to Reduction of Acid Secretion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 57-58 (1986).
B36	LIND, et al., "Long-Term Acid Inhibitory Effect of Different Daily Doses of Omeprazole 24 Hours After Dosing", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 137-138 (1986).
B37	MARDH, Sven, "Omeprazole Inhibits the Formation of Acid in the Parietal Cell by a Direct Inhibition of the H <sup>+</sup> -K <sup>+</sup> -ATPase, the Acid Pump of the Stomach", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 49-51 (1986).
B38	MATTSSON, et al., "Effect of Omeprazole on Gastric Mucosal Blood Flow in the Rat", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 72-74 (1986).
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B43	NIELSEN, et al., "Immediate Effect of Omeprazole and Cimetidine on Apparent Liver Blood Flow in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 166-168 (1986).
B44	OKABE, et al., "Effects of Omeprazole on Gastric Secretion and Experimental Ulcers in Rats", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 75-76 (1986).
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B46	PECKMAN, "Alternative Method for Administering Proton-Pump Inhibitors Through Nasogastric Tubes", American Journal of Health-System Pharmacists, Vol. 56, p. 1020 (May 15, 1999).
B47	POULSEN, et al., "Omeprazole Accelerates Healing of Cysteamine Induced Duodenal Ulcers in Rat", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 77-78 (1986).
B48	POUNDER, et al., "Twenty-Four Hour Intragastric Acidity during Treatment with Oral Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 108-116 (1986).
B49	Prilosec Production Information, Rev. 07/05, submitted with NDA 19-810.
B50	REGARDH, C.S., "Pharmacokinetics and Metabolism of Omeprazole in Man", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 99-104 (1986).
B51	ROHNER, et al., "Oral Omeprazole, 20 mg Versus 30 mg Once Daily: Effect on Healing Rates in 115 Duodenal Ulcer Patients", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 173-174 (1986).
B52	RYBERG, et al., "Gastric Acid Secretion and Plasma Gastrin Levels in Dogs Treated with High Oral Doses of Ranitidine and Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 94-95 (1986).
B53	SACHS, George, "The Parietal Cell as a Therapeutic Target", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 1-10 (1986).
B54	SACHS, et al., "Discussion", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, p. 17 (1986).
B55	SEWING, et al., "Effect of Substituted Benzimidazoles on H <sup>+</sup> -K <sup>+</sup> -ATPase of Isolated Guinea-pig Parietal Cells", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 52-53 (1986).
B56	SHARMA, et al., "Acid Secretory Capacity After Treatment with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 143-144 (1986).
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B58	SHEARMAN, et al., "Effect of Omeprazole on Gastric Emptying in Patients with a History of Duodenal Ulceration", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 164-165 (1986).
B59	SKANBERG, et al., "Pharmacokinetics and Metabolism of Omeprazole in Animals", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 92-93. (1986).
B60	SMALLWOOD, et al., "Double-Blind Comparison of Omeprazole, 10 mg Versus 30 mg, for Healing Duodenal Ulcers", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 171-172 (1986).
B61	SOLVELL, Lennart, "Safety Aspects of Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 129-133 (1986).
B62	SUNDELL, et al., "Structure and Function of the Dog Gastric Mucosa During and After a 1-Year Treatment with Omeprazole. II. Effects on Gastric Acid Secretion and Blood Levels of Gastric Hormones", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 82-85 (1986).
B63	SUNDLER, et al., "Inhibition of Gastric Acid Secretion by Omeprazole and Ranitidine. Effects on Plasma Gastrin and Gastric Histamine, Histidine Decarboxylase Activity and ECL Cell Density in Normal and Antrectomized Rats", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 39-45 (1986).
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B65	WALAN, Anders, "Treatment of Duodenal Ulcer Disease. Clinical Results with Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 118-121 (1986).
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B67	WALLMARK, Bjorn, "Mechanism of Action of Omeprazole", Scand. J. Gastroenterology, Vol. 21, Suppl. 118, pp. 11-16 (1986).
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B71	YEOMANS, et al., "Morning or Evening Dosing with Low-Dose Omeprazole: Effects on 24-Hour Gastric Acidity Profiles in Duodenal Ulcer Patients", Scand. J.

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		Gastroenterology, Vol. 21, Suppl. 118, pp. 152-153 (1986).
	B72	Zegerid Product Information, February 2006.
	B73	November 13, 2007 Detailed Statement of the Factual and Legal Bases from Par Pharmaceutical to Santarus, Inc. and The Curators of the University of Missouri.
	B74	December 6, 2007 Detailed Statement of the Factual and Legal Bases from Par Pharmaceutical to Santarus, Inc. and The Curators of the University of Missouri.
	B75	December 20, 2007 Complaint for Patent Infringement, Santarus, Inc. and The Curators of the University of Missouri v. Par Pharmaceutical with Exs. A-E, Case No. 07-827 (D. Del.).
	B76	December 20, 2007 Report of the Filing or Determination of an Action Regarding a Patent or Trademark, Case No. 07-827-GMS (D. Del.).
	B77	January 10, 2008 Answer Filed by Par Pharmaceutical, Case No. 07-827-GMS (D. Del.).
	B78	June 16, 2008 Par's Objection and Responses to Curators of the University of Missouri's 1st Set of Requests for Production of Documents, Case No. 07-551-GMS (D. Del.).
	B79	June 23, 2008 Reponses and Objections of Tap Pharmaceutical Products Inc. to Defendant's Subpoena, Case Nos. 07-551-GMS and 07-827-GMS (D. Del.).
	B80	June 26, 2008 Final Joint Claim Construction Chart, Case No. 07-551-GMS (D. Del.).
	B81	July 9, 2008 Santarus' Responses to Par Pharmaceutical First Set of Interrogatories, Case No. 07-551-GMS (D. Del.).
	B82	August 22, 2008 Defendant Par Pharmaceutical, Inc.'s Opening Claim Construction Brief Regarding U.S. Patent Nos. 6,489,346; 6,699,885; and 6,645,988, Case No. 07-551-GMS (D. Del.).
	B83	August 26, 2008 Plaintiff's Opening Claim Construction Brief, Case No. 07-551-GMS (D. Del.).
	B84	September 22, 2008 Defendant's Answering Brief Regarding Claim Construction, Case No. 07-551-GMS (D. Del.).
	B85	September 22, 2008 Declaration of Steven J. Fineman, Case No. 07-551-GMS (D. Del.).
	B86	September 22, 2008 Plaintiff's Answering Brief Regarding Claim Construction, Case No. 07-551-GMS (D. Del.).

		Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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